EXHIBIT 18

CONFIDENTIAL

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL No. 2804 Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al. Case No. 18-op-45090	
The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al Case No. 17-op-45004	

EXPERT REPORT OF HOWARD L. DORFMAN
MAY 10, 2019

I. INTRODUCTION

A. Qualifications

1. My name is Howard L. Dorfman. I am an Adjunct Professor and Distinguished Practitioner at Seton Hall University School of Law located in Newark, New Jersey. Seton Hall University School of Law is a nationally ranked law school with a concentration in health law and compliance where I teach in the Health Law and Healthcare Compliance programs.

2. Previously and beginning in 1978, I served in various senior capacities in national and international companies in the health sector. I served as Vice President and General Counsel at Ferring Pharmaceuticals, Inc. in Parsippany, New Jersey, where I was responsible for all legal matters relating to the U.S. affiliate of the Swiss-based global pharmaceutical and biotechnology company. I also served as Senior Vice President and General Counsel of U.S. operations of Turing Pharmaceuticals, LLC where I supervised all legal activities and served as interim Chief Compliance Officer responsible for developing a compliance blueprint for the company. Previously, I served as Counsel in the Life Sciences group at Ropes & Gray LLP in New York, where I focused on the pharmaceutical, medical device, and biotechnology industries.

3. My areas of professional concentration and experience include Food and Drug Administration ("FDA") regulatory law, fraud and abuse, compliance programs, and risk management processes. Prior to my association with Ropes & Gray, I was chief legal officer of the pharmaceutical division of Bayer Healthcare LLC ("Bayer"), where I was responsible for legal oversight relating to the commercial, regulatory, and compliance

activities of the company's pharmaceutical operations. Before joining Bayer, I worked at Bristol-Myers Squibb ("BMS"), where I first served as Counsel in the litigation department and subsequently as Counsel to the company's U.S. pharmaceutical operations. There I developed the first compliance training program for the Medical Science Liaisons.

4. I have established Office of Inspector General ("OIG") mandated compliance processes and Standard Operating Procedures ("SOPs") at major pharmaceutical and biotechnology companies and start-ups and provided counseling on regulatory, compliance, and risk management issues as well as advising companies on compliance with the Foreign Corrupt Practices Act ("FCPA"). I have lectured and published articles on a range of regulatory, compliance, and product liability issues.

5. I received my B.A. with honors from Yeshiva University and my J.D. from Brooklyn Law School. I am admitted to practice law in New York and New Jersey and a member of the Bar of the United States Supreme Court. My CV is attached as Appendix A to this report.

B. Assignment

6. I have been retained by counsel for Teva Pharmaceuticals USA, Inc. ("Teva USA"), Cephalon, Inc. ("Cephalon"), Actavis Pharma, Inc. ("Actavis Pharma"), Actavis LLC ("Actavis LLC"), Watson Laboratories, Inc. ("Watson"), and other affiliates[1] to serve as an expert witness in this case.

[1] Teva USA and Cephalon are referred to as the "Teva Defendants." Actavis Pharma, Actavis LLC, Watson, Warner Chilcott Company, LLC, Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic

physician recall of marketing messages delivered by Cephalon's sales force.[25] The findings of the message recall studies were again summarized in the annual reports to the OIG and included any off-label findings, a description of the actions Cephalon took or planned to take in response to any off-label findings, and the underlying records of the detailing interactions.[26]

IV. OPINION #1: CEPHALON IMMEDIATELY ADDRESSED AND IMPLEMENTED INTERNAL POLICIES AND PROCEDURES CONSISTENT WITH THE PRINCIPLES FIRST ENUNCIATED BY OIG IN 2003. BY AT LEAST 2006, CEPHALON INSTALLED A SALES AND MARKETING COMPLIANCE PROGRAM THAT MET AND OFTEN EXCEEDED THE STANDARDS SET FORTH BY THE OIG GUIDANCE.

32. Following the issuance of OIG Guidance in 2003, Cephalon successfully enhanced and refined its existing policies to incorporate the new provisions suggested by OIG Guidance. A review of internal Cephalon documents regarding policies developed in the wake of the OIG Guidance reveals a consistent effort to maintain a rigorous compliance program. By at least October 2006, Cephalon had put in place a compliance process that met and often exceeded each of the principles set forth by the OIG Guidance.

33. The policies and procedures developed and implemented by Cephalon, as discussed in greater detail below, address the most significant concerns consistently expressed by OIG relative to the societal benefits to be derived from an effective compliance program and the methods by which these policies and procedures can reduce the risk of prosecution. In my opinion, these are (1) Does the activity have the potential to interfere with or undermine the independent clinical judgement of a HCP in determining the appropriate

[25] CIA, § III.J.

[26] CIA Annual Report Year 1, TEVA_MDL_A_00561764-2290, at TEVA_MDL_A_00561764 (2009).

course of therapy? (2) Does the activity have the potential to increase reimbursement costs to the federal health care programs? (3) Does the arrangement have the potential to increase overutilization or inappropriate utilization of the company's therapies? (4) Does the arrangement raise issues and concerns regarding patient safety or quality of care?[27]

A. Hiring of a Chief Compliance Officer and Reorganization of Global Compliance Committee

34. In May 2004, Cephalon hired a Chief Compliance Officer ("CCO") to oversee all compliance initiatives.[28] Cephalon then changed its corporate reporting structure so that the CCO reported directly to the CEO and Audit Committee, rather than the General Counsel.[29] Compliance with this particular OIG recommendation speaks to Cephalon's commitment to a robust compliance function. Any reporting arrangement that could impede the free flow of information from the CCO, such as having the CCO report to the General Counsel or Chief Legal Officer, could lead to assertions of privilege that could delay timely reporting of compliance-related issues and negatively affect the compliance program in such areas as auditing, monitoring, and investigations.

35. In addition, Cephalon revamped its Global Compliance Committee by adding new members and clarifying its purpose via a new charter, which set forth the committees' directives, including, but not limited to, "provid[ing] guidance and support to the Chief Compliance Officer and the Global Compliance Program," "support[ing] Cephalon's

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[27] OIG Guidance, p. 15.

[28] 2004 Mid-Year Compliance Update, TEVA_MDL_A_06377159-81, at TEVA_MDL_A_06377163 (July 29, 2004).

[29] 2004 Mid-Year Compliance Update, TEVA_MDL_A_06377159-81, at TEVA_MDL_A_06377164 (July 29, 2004).

compliance effort across all departments and functions," and "foster[ing] and support[ing] ethical conduct by Cephalon employees and agents."[30]

36. Further, while Cephalon had a committee in place since 1999 to review and approve promotional, advertising, and labeling materials for FDA products,[31] Cephalon implemented a number of enhancements in the 2008 and 2009 time period, including implementing a formal policy that outlines the steps that any promotional material must go through prior to being approved for use.[32] This included review and approval by Cephalon's established Promotional & Disease Review Committee ("PDRC"). All promotional materials – *i.e.,* any material that could be used in promotion with HCPs, among other content – needed to be reviewed by the PDRC (which was later changed to the Promotion and Advertising Review Committee ("PARC")).[33]

37. The PDRC was tasked with ensuring each piece of promotional material was accurate and not misleading; made claims about a product only when properly medically substantiated; accurately reflected the balance between risks and benefits; was consistent with other applicable FDA requirements; and reflected appropriate taste consistent with

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[30] Charter of Cephalon's Global Compliance Committee, TEVA_MDL_A_00819644-45, at TEVA_MDL_A_00819644 (January 2009).

[31] In 1999, prior to Cephalon ever selling an opioid product, Cephalon created the Promotional Review Committee to review and approve promotional, advertising, and labeling materials for FDA-approved products. *See* Review and Approval of Promotional Materials (SOP-0348-R01), Teva_MDL_A_04785055-62. The name of this committee later changed to the Promotional & Disease Review Committee, which is referenced in Cephalon's March 2007 Policy on Promotional Materials and Activities. That policy makes clear that all promotional materials and branded press releases, must be submitted to the PDRC for review and approval and that sales representatives may only use PDRC approved materials when detailing a Cephalon product. Policy on Promotional Materials and Activities, TEVA_MDL_A_01251780-89.

[32] Promotional Review Process (GPO-110), TEVA_MDL_A_00552513-25 (Jan. 26, 2009).

[33] Promotional Review Process Training, TEVA_MDL_A_08923233-98, at TEVA_MDL_A_08923235, (Dec. 16, 2008); Cephalon created the Promotional Review Process GPO-110 to outline the PDRC review process.

Cephalon's values.[34] Additionally, many of Cephalon's promotional materials were sent to the Food and Drug Administration's Division of Drug Marketing, Advertising and Communications ("DDMAC") for review and approval prior to distribution.[35]

38. PDRC reviewers consisted of members from four functional areas, each with a unique responsibility. These areas included: Marketing, Regulatory, Legal, and Medical.[36] Each reviewer was expected to provide formal feedback with supporting rationale and approval in their functional area. Reviewers could, however, make informal comments outside their functional area.[37] When PDRC review was necessary, a tracking number and form was required for the project; this allowed Cephalon to easily monitor a document as it was developed into final form and to ensure that only documents approved by the PDRC were used in promoting the company's products.[38]

39. These steps by Cephalon meet or exceed all of the recommendations of the relevant elements within the OIG Guidance.

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[34] Promotional Review Process Training, TEVA_MDL_A_08923233-98, at TEVA_MDL_A_08923240, (Dec. 16, 2008).

[35] Promotional Review Process (GPO-110), TEVA_MDL_A_00552513-25 (Jan. 26, 2009).

[36] Promotional Review Process Training, TEVA_MDL_A_08923233-98, at TEVA_MDL_A_08923239, (Dec. 16, 2008).

[37] Promotional Review Process Training, TEVA_MDL_A_08923233-98, at TEVA_MDL_A_08923240 (Dec. 16, 2008).

[38] Promotional Review Process Training, TEVA_MDL_A_08923233-98, at TEVA_MDL_A_08923245, (Dec. 16, 2008).

B. Revision to Code of Conduct and Development of Written Compliance Polices Regarding Marketing and Sales

40. In May 2004, Cephalon revised its Code of Conduct to cover a wide array of compliance issues, including those pertaining to the marketing and sale of its prescription medicines. The revised Code of Conduct reinforced many of Cephalon's existing policies. Specifically, it prohibited violations of FDA regulations and company policies and required employees to report violations through various mechanisms, including an anonymous compliance hotline.[39] Cephalon required all employees to certify annually that they had read, understood, and would abide by the terms of the document.[40]

41. ***The 2004 Sales Policy Handbook.*** In 2004, consistent with its commitment to ensure compliance with applicable legal requirements and the OIG guidance, Cephalon developed a Sales Policy Handbook ("2004 Handbook") which contained ten compliance ground rules and 11 specific policies concerning the sales and marketing of Cephalon's products.41 The Handbook outlined internal compliance standards related to off-label promotion and fraud and abuse/anti-kickback concerns with the goal of "provid[ing] enhanced guidance to [Cephalon employees] on appropriate promotional practices."42 The Handbook emphasized that Cephalon was committed to upholding more conservative compliance standards than those set by existing legal requirements, reminding employees to "adhere to the Company standard[s] notwithstanding the fact the

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[39] 2004 Cephalon Code of Conduct, TEVA_MDL_A_09624030-698, at TEVA_MDL_A_09624194 and TEVA_MDL_A_09624196 (2004).

[40] 2004 Cephalon Code of Conduct, TEVA_MDL_A_09624030-698, at TEVA_MDL_A_09624196 (2004).

[41] 2004 Sales Policy Handbook, TEVA_MDL_A_04794285-294, at TEVA_MDL_A_04794294 (Oct. 2004).

[42] 2004 Annual Compliance Update (December 16, 2004), which was part of the December 16, 2004 Board of Directors Meeting, TEVA_MDL_A_00667543-754, at TEVA_MDL_A_00667613.

law may permit 'more aggressive' conduct."[43] Specifically, the 2004 Handbook called on employees to "[k]now and follow the letter and spirit of the Compliance Policies applicable to your job and our industry," "avoid conduct risking involvement in any unlawful practice," and "report violations, even in awkward and uncomfortable situations," among other requirements.[44]

42. In particular, the 2004 Handbook emphasized compliance "with all applicable laws and regulations" and adherence "to good faith and professional standards in the conduct of its marketing and promotional activities."[45]

43. In addition to providing an overview of the laws and standards that affect the sales and marketing of Cephalon Products, the 2004 Sales Policy Handbook references 11 specific policies that were in place at the time and for which sales representatives were required to follow. These policies include: (1) Policy on Advertising and Promotional Materials and Activities,[46] (2) Policy on Identifying Called on Universe of Physicians in Connection with Promotional Activities,[47] (3) Policy Regarding Medical Information Request Forms,[48] (4) Policy on Gifts, Meals and Entertainment for Physicians and Other Healthcare Practitioners,[49] (5) Policy on Promotional Meetings,[50] (6) Policy on

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[43] 2004 Sales Policy Handbook, TEVA_MDL_A_04794285-294, at TEVA_MDL_A_04794287 (Oct. 2004)

[44] 2004 Sales Policy Handbook, TEVA_MDL_A_04794285-294, at TEVA_MDL_A_04794292 - TEVA_MDL_A_04794293 (Oct. 2004).

[45] 2004 Sales Policy Handbook, TEVA_MDL_A_04794285-294, at TEVA_MDL_A_04794287 (Oct. 2004).

[46] TEVA_MDL_A_11 892858-61.

[47] TEVA_MDL_A_11 892862-64.

[48] TEVA_MDL_A_11 892865-70.

[49] TEVA_MDL_A_11 892871-74.

[50] TEVA_MDL_A_11 892876-82.

Preceptorships,[51] (7) Policy on Funding to Support Independent Third-Party Educational or Scientific Meetings,[52] (8) Policy on Grants or Support that Are not for Independent Medical Education,[53] (9) Policy re: Sample Management,[54] (10) Policy re: Employeee Reporting of Adverse Events, Product Complaints, Tampering Adulteration and/or Diversion,[55] and (11) Policy on Providing Reimbursement Information to Customers.[56]

44. These policies provide specific guidance and make clear the boundaries of appropriate versus inappropriate promotion and conduct. By way of a few examples:

45. *Promotional Activity.* Among other direction, the 2004 Policy on Advertising and Promotional Materials and Activities makes clear that all promotional materials must be reviewed and approved by Cephalon's Promotional Review Committee and that "no Cephalon sales representative may promote any unapproved Company product or approved product for an unapproved use."[57] In addition, Cephalon required its sales and marketing employees to discuss Cephalon products "in conformity with the approved product labeling, which includes, among other areas, approved indications, contraindications, warnings, and mechanism of action . . ." and provide "appropriate information and education to physicians through permissible means, including with

[51] TEVA_MDL_A_11892883-86.

[52] TEVA_MDL_A_11892887-99.

[53] TEVA_MDL_A_11892900-03.

[54] TEVA_MDL_A_11892875.

[55] TEVA_MDL_A_11892904-06.

[56] TEVA_MDL_A_11892838-39.

[57] TEVA_MDL_A_11892858-61, at TEVA_MDL_A_11892858.

respect to clinical studies regarding our products."[58] As part of that instruction, the 2004 policy reaffirms that off-label discussions are not prohibited — "[s]ales representatives may not transition from one permitted topic (such as approved indications) to another permitted topic or action (such as handing a reprint of an article to a physician) in a manner which improperly suggests that Company products are safe and effective for indications other than those in our approved labeling."[59]

46. *Policy on Funding to Support Independent, Third Party Educational or Scientific Meetings (e.g., CMEs).* In its 2004 policy concerning support for independent third party organizations, among other directions, Cephalon makes clear that the program provider must maintain control over the content of the program and that "Cephalon employees may not prepare scripts for speakers, target points for emphasis, or otherwise attempt to influence the content of the program."[60] The policy prevents any influence by Cephalon over any medical education.

47. *Grant Policy.* In addition to a policy governing independent medical education grants, Cephalon also had a policy for grants or support that are not for independent medical education.[61] This policy makes clear that "no grant or contribution can be made to reward or influence any individual practitioner's prescribing or an institution's formulary treatment for Cephalon's products."[62]

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[58] Id.

[59] TEVA_MDL_A_11892858-61, at TEVA_MDL_A_11892859..

[60] TEVA_MDL_A_11892887-99, at TEVA_MDL_A_11892887.

[61] TEVA_MDL_A_11892900-03, TEVA_MDL_A_11892900.

[62] Id.

48. *Promotional Speakers*. In line with recommendations from the OIG Guidance, Cephalon instituted and maintained a robust policy regarding the selection, contracting, and training of its promotional speakers. As early as 2004, the Company had put in place an identification and approval process for potential additions to its Speaker Bureau to ensure speakers are actively involved in patient care, have extensive experience in the relevant disease state or therapeutic area, have experience with the Cephalon product in the therapeutic area about which the speaker will lecture, and are not listed on the OIG exclusion list.[63] In addition, the policy required all speakers to complete live trainings on subjects including, but not limited to, product labeling, approved slide kits, FDA and OIG regulations, and risk minimization plans before giving presentations on Cephalon products.[64]

49. These are just a few examples of the clear guidance provided by Cephalon in its 2004 compliance policies. Based on my many years of experience in developing and evaluating compliance programs for adherence to OIG guidelines, the policies set forth in the 2004 Sales Policy Handbook were consistent with industry practices at that time for well-designed, written policies to address compliance with the various laws and regulations that govern the sale and promotion of pharmaceutical products.

50. ***Updates to the Sales Policy Handbook and Other Policy Updates***. Cephalon reviewed and revised its policies in 2006 when it updated its Sales Policy Handbook and related policies.[65] It again reviewed and revised its policies and issued another update in June

[63] Cephalon Speaker Bureau Policy (2004), TEVA_MDL_A_00552396-420, at TEVA_MDL_A_00552396.

[64] Cephalon Speaker Bureau Policy (2004), TEVA_MDL_A_00552396-420, at TEVA_MDL_A_00552396.

[65] 2006 Sales Policy Handbook, TEVA_MDL_A_01251767-77, at TEVA_MDL_A_01251775 (Oct. 2006).

2007 when Cephalon released its Marketing Policy Handbook.[66] The fact that Cephalon revisited, reviewed, and revised is sales and promotional policies further demonstrates that Cephalon was committed to following OIG Guidance's recommendations and that Cephalon's policies were meeting or exceeding those recommendations. Indeed, Cephalon continued to review and refine its policies throughout this period and leading up to the implementation of the CIA, as well as afterwards. By way of a few examples:

51. *Promotional Activity.* In Cephalon's March 2007 update to the Policy on Promotional Materials and Activities, Cephalon provides a more detailed guide to maintain compliance during sales calls, both in general and in regards to specific products. The March 2007 policy makes clear that "if the HCP raises an off-label use… the sales representative should steer the conversation away from the specific disease state identified by the HCP and instead focus on the attributes and clinical benefits of the Cephalon product," and "[a] sales representative should use the [Medical Information Request Form] process… for questions initiated by the HCP that are off-label."[67] The March 2007 policy also contained sales call guidance specific to Fentora, noting that a sales representative must focus the body of his or her call on breakthrough cancer pain.[68]

52. *Gifts, Meals, and Entertainment.* Likewise, the October 2006 update to the Policy on Gifts, Meals, and Entertainment for Physicians and other Health Care Practitioners

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[66] Marketing Policy Handbook (June 2007), TEVA_MDL_A_00552840-49.

[67] Policy on Promotional Materials and Activities (March 2007), Teva_MDL_A_06880605-14, at Teva_MDL_A_06880606. The Medical Information Request Form ("MIRF") is a form that sales representative provide to HCPs in response to an unsolicited request for off-label information. The form would document the unsolicited nature of the request, identify the HCP's specific request, and allow monitoring and follow-up as appropriate.

[68] Policy on Promotional Materials and Activities (March 2007), Teva_MDL_A_06880605-14, at Teva_MDL_A_07880612.

provides additional detail and guidance on the policy concerning gifts, meals, and entertainment for physicians and other HCPs so that it continued to meet industry best practices. Key tenets included balancing the volume of in- and out-of-office meals, moderating the cost per attendee of meals and entertainment, and ensuring all meals and events remain centered on appropriate discussion of the relevant product.[69]

53. Cephalon re-iterated its compliance policy with respect to meals and entertainment in its Good Business Practices Field Guide ("GBP") and continued to emphasize the company's "We don't buy business," approach.[70] For example, the GBP makes clear that sales employees should not target high prescribers with expensive meals and entertainment. In fact, the GBP states that employees faced "with a choice of two options: a more expensive choice and a less expensive choice . . . are expected to choose the less expensive option."[71]

54. *Promotional Speakers.* Cephalon updated its Speaker Bureau Policy in June 2007. To ensure continued compliance, the updates reinforce that once a speaker is selected as a member of the bureau, Cephalon promotional speakers are held to rigorous standards, particularly with regards to off-label promotion. Among other direction, the policy makes clear that all speaker materials must be approved by the PDRC committee, that speakers are not permitted to make any changes to any slides in the approved slide-deck,

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[69] Policy on Gifts, Meals, and Entertainment for Physicians and other Health Care Practitioners (October 2006), TEVA_MDL_A_04756815-21.

[70] The Good Business Practice Field Guide (June 2008), TEVA_MDL_A_00552305-63. The GBP was developed by the CNS and PCS Sales Organization to provide guidance and clarify expectations for specific business behavior in the field. *Id.* The fact that Cephalon chose to reinforce and elaborate on its formal policies through the GBP is another factor that shows Cephalon was meeting or exceeding OIG guidelines.

[71] The Good Business Practice Field Guide (June 2008), TEVA_MDL_A_00552305-63, at TEVA_MDL_A_0552331.

and that all speaker programs must begin with a substantive "on-label" discussion. The policy also provides direction on how a speaker may appropriately answer an unsolicited off-label question.[72]

55. ***Good Business Practices Field Guide ("GBP").*** Cephalon enhanced and reinforced its written policies by issuing a Good Business Practices Field Guide in June 2008, which provides additional detail, context and explanation of its formal policies. Specifically, the GBP provides further guidance and clarifies expectations for specific business behavior in the field by sales representatives. The GBP provides comprehensive requirements for sales representatives regarding: (1) promotional activities;[73] (2) meals and gifts;[74] (3) speaker programs;[75] (4) targeting and call activity;[76] and (5) Reimbursement and Managed Care.[77] Each section of the GBP contains "recommended" and "not recommended" strategies, as well as Q &A's on some of the most salient compliance issues.

56. ***US Sales and Marketing Policy***. In July 2008, Cephalon issued a U.S. Sales and Marketing Policy.[78] The policy is applicable to all U.S. Cephalon employees whenever

[72] Marketing Speaker Bureau (CSP) Policy (June 2007), TEVA_MDL_A_00954145-69.

[73] Good Business Practices Field Guide ("GBP"), TEVA_MDL_A_00552305-63, at TEVA_MDL_A_00552316-20 (June 2008).

[74] Good Business Practices Field Guide ("GBP"), TEVA_MDL_A_00552305-63, at TEVA_MDL_A_00552323-34 (June 2008).

[75] Good Business Practices Field Guide ("GBP"), TEVA_MDL_A_00552305-63, at TEVA_MDL_A_00552332 and TEVA_MDL_A_00552336-50. (June 2008).

[76] Good Business Practices Field Guide ("GBP"), TEVA_MDL_A_00552305-63, at TEVA_MDL_A_00552351-54 (June 2008).

[77] Good Business Practices Field Guide ("GBP"), TEVA_MDL_A_00552305-63, at TEVA_MDL_A_00552355-63. (June 2008).

[78] U.S. Sales and Marketing Policy, TEVA_MDL_A_00552786-818 (July 2008).

they are interacting with healthcare professionals and organizations. The policy makes clear that failure to comply with the letter or spirit of the company's policy may lead to disciplinary action including termination. The two basic principles of the policy are: (1) "Our promotional messages are on-label, truthful and fair balanced," and (2) "We do not buy business." The 2008 US Sales and Marketing Policy reiterates the rules for and provides additional guidance to employees regarding promotional activities, meals and gifts, hiring health care professionals, third-party grant requests, and reimbursement support.[79]

57. Ultimately, by 2008, Cephalon had adopted and implemented a number of policies, including those listed in Appendix C.

58. There is little doubt that Cephalon acted in a timely manner to address compliance standards following the release of the OIG Guidance and, in fact, did do so. The continuing revisions and additions to the Cephalon policies and procedures, including with respect to promotional interactions with HCPs, demonstrated Cephalon's commitment to monitor and address evolving compliance issues.

C. Establishing and Maintaining a Compliance Hotline and Enforcement of Compliance Policy

59. Cephalon introduced a compliance hotline in early 2003 that allowed employees to report possible compliance violations either on a named or anonymous basis.[80] To encourage reporting and reduce the risk of retaliation, Cephalon engages a third-party vendor to be

[79] U.S. Sales and Marketing Policy, TEVA_MDL_A_00552786-818 (July 2008).

[80] Mid-Year Compliance Update, TEVA_MDL_A_06377159-81, at TEVA_MDL_A_06377165 (July 29, 2004).

the first line of response for hotline calls.[81] The company also retains a log of each complaint containing the reporting employee's name (if not anonymous), investigator name, date of incident report, a brief statement of the incident, the resolution or remediation, and the date of incident close.[82]

60. According to the log of complaints provided by Cephalon, there were approximately eighteen incidents related to Actiq and thirteen related to Fentora between 2003 and 2008. Although most of these incidents resulted in findings of no improper conduct or a written warning, the log shows that Cephalon investigated each complaint promptly with an eye toward diligent enforcement. For example, in March 2005, a DEA agent alleged that a physician had remarked that a Cephalon sales representative indicated "it was okay to use Actiq for rheumatoid arthritis and degenerative joint arthritis."[83] Within twenty-four hours of receiving the complaint, Cephalon contacted the physician who then "indicated that he did not make these statements and that he believes Cephalon's promotion has been consistent with the label."[84]

61. In another case, a pharmacist contacted the hotline in December 2007 to report that a representative had provided an Actiq placebo to a physician even though placebos should have been used or destroyed prior the end of 2006.[85] Within a week, Cephalon had

[81] Mid-Year Compliance Update, TEVA_MDL_A_06377159-81, at TEVA_MDL_A_06377165 (July 29, 2004).

[82] TEVA_MDL_A_06616796-855

[83] TEVA_MDL_A_06616796-855, at 6806.

[84] Id.

[85] TEVA_MDL_A_06616796-855, at 6854.

contacted the prescribing physician and pharmacist and discovered that the physician had actually provided the placebo, not the representative.[86]

62. These and other hotline entries unrelated to Actiq or Fentora illustrate Cephalon's "development of policies and procedures for the investigation of identified instances of noncompliance and misconduct" as well as "initiation of appropriate corrective action and preventive measures. . .," as set forth in the OIG Guidance.[87] For example, in August 2004, Cephalon placed an employee on 60-day probation and long-term monitoring for making "certain promotional claims . . .which were not consistent with FDA label [sic]."[88]

63. In another incident involving a complaint that a sales representative had made off-label claims, Cephalon mandated compliance counseling from the Chief Compliance Officer and the representative's direct manager, sent a memo "detailing the representative's deficiencies and further indicating violations of Cephalon policies would subject the representative to additional discipline," and required the representative to retake internal compliance training as well as "ride with the area trainer for additional training."[89] In another case, Cephalon terminated a representative following investigation and confirmation of a serious violation of the Policy on Meals, Gifts, and Entertainment.[90] This again demonstrates Cephalon's compliance with the OIG Guidance during the period between 2003 and 2008.

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[86] Id.

[87] OIG Guidelines, p. 8.

[88] TEVA_MDL_A_06_616796-855, at 6796.

[89] TEVA_MDL_A_06_616796-855, at 6799-6800.

[90] TEVA_MDL_A_06_616796-855, at 6801.

D. Establishing and Maintaining Effective Training Programs

64. As early as 2004, the Cephalon Legal Department had implemented an Investigations Training Handbook designed to acquaint sales management with the requirements of proper compliance and employment investigation.[91] In May 2004, at the National Manager Meeting, the Legal Department used this Handbook to train all sales managers on appropriate promotional and detailing practices so that these managers could train their representatives at the June 2004 Plan of Action meeting.[92]

65. Over the same period, Cephalon implemented a company-wide Learning Management System ("LMS") for training and policy dissemination to all employees including Sales. LMS rolled out training materials (including compliance policies and procedures) to all employees and tests for employees to gauge their comprehension of such materials.[93] Furthermore, LMS simplifies the tracking process by which the company could identify employees with incomplete training.[94] In a similar vein, LMS tracks employees' roles during their tenure such that it would automatically notify an employee of additional training requirements as a result of a change in position.[95]

66. In 2005, Cephalon also launched Ethics Connect, an electronic learning management system of training modules for all employees, including the sales force. To fulfill their

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[91] 2004 Mid-Year Compliance Update Memo, TEVA_MDL_A_06377159-81 (July 29, 2004).

[92] Id.

[93] 2004 Mid-Year Compliance Update Memo, TEVA_MDL_A_06377159-81, at TEVA_MDL_A_06377166 (July 29, 2004).

[94] 2004 Mid-Year Compliance Update Memo, TEVA_MDL_A_06377159-81, at TEVA_MDL_A_06377166 (July 29, 2004).

[95] 2004 Mid-Year Compliance Update Memo, TEVA_MDL_A_06377159-81, at TEVA_MDL_A_06377166 (July 29, 2004).

training requirements, employees have to complete a required number of modules per year.[96] In order to fulfill their Ethics Connect requirements, employees also have to sign electronically an acknowledgment stating they will comply with the company's Code of Conduct and Standards of Business Conduct.[97]

67. In April 2006, Cephalon's Sales Training and Development Department updated their training processes to ensure sales employees understood compliance requirements associated with product promotion.[98] The updated training requires newly-hired sales employees to complete a three-phase training program on product information, department policies, and compliance procedures.[99] Also, it mandates all sales employees to score 90 percent or higher on an annual certification exam testing knowledge of the sale and effective use of Cephalon products. Employees scoring under 90 percent are not allowed to promote company products.[100]

68. In June 2007, as part of the Marketing Speaker Bureau (Certified Speaking Professionals ("CSP")) Policy, all Cephalon speakers are required to go through training on compliance with FDA and OIG regulations. In particular, the company trains speakers on the appropriate ways to address unsolicited off-label questions posed during Q&A portions of speaker programs. The published CSP policy emphasizes that doctors do not have to

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[96] Cephalon Newsletter (Summer 2005), TEVA_MDL_A_08272952.

[97] Standards of Business Conduct, TEVA_MDL_A_06880695-710, at TEVA_MDL_A_06880697 (Oct. 4, 2007).

[98] Training Process for Members of the Sales Organization (SOP-0001044), TEVA_MDL_A_01249224-28 (April 6, 2006).

[99] Training Process for Members of the Sales Organization (SOP-0001044 TEVA_MDL_A_01249224-28 (April 6, 2006).

[100] Training Process for Members of the Sales Organization (SOP-0001044), TEVA_MDL_A_01249224-28 (April 6, 2006).

answer any off-label questions, but recognizes a speaker may provide a verbal answer to an off-label question as long as the speaker believes he or she can provide an objective, scientifically accurate, and balanced response. However, the training materials within the policy make clear that Cephalon sales representatives are not to recommend or suggest the speaker address any off-label uses of the product.[101]

69. A Cephalon presentation titled "Understanding FDA Regulations" describes how Cephalon has long been committed to compliance by focusing on FDA regulations and states "[e]very year our company objectives begin with compliance – all activities must be in compliance with laws and Company Policies." The presentation also provides an overview of the Food, Drug & Cosmetic Act and the "very specific, limited circumstances" when information about off-label uses is appropriate.[102] The presentation explains that manufacturers may be able to provide additional information about their products to further scientific exchange (such as MIRFs for unsolicited inquiries and presentations of studies at scientific forums). It further instructs that when the physician raises questions about off-label product use, the representative should make full use of MIRFs, refer the physician to colleagues with knowledge in the area being questions, and make appropriate use of WLF reprints. Representatives should not imply that the product is indicated for something that it is not.[103]

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[101] Marketing Speaker Bureau (CSP) Policy, TEVA_MDL_A_00954145-69 (June 2007).

[102] "Understanding FDA Regulations," TEVA_MDL_A_02724063.

[103] "Understanding FDA Regulations," TEVA_MDL_A_02724063. The Washington Legal Foundation ("WLF") decision held that FDA's restriction preventing pharmaceutical companies from providing off-label information violated the provisions of the First Amendment applicable to protected Commercial Free Speech. This opinion was later formalized in two FDA Guidance documents and justified the dissemination of appropriate scientific information to HCPs. Accordingly, Cephalon developed a procedure whereby an HCP could obtain a medical reprint from a sales representative.

70. The policies and procedures developed and implemented by Cephalon address the most significant concerns consistently expressed by OIG. As stated elsewhere, these concerns manifest themselves in the following goals: eliminating the potential to interfere with or undermine the independent clinical judgement of an HCP in determining the appropriate course of therapy; eliminating the potential to increase reimbursement costs to the federal health care programs; eliminating the potential to increase overutilization or inappropriate utilization of the company's therapies; and preventing arrangements that raise issues and concerns regarding patient safety or quality of care.

V. OPINION #2: CEPHALON MADE FURTHER COMPLIANCE ENHANCEMENTS BEFORE, AS PART OF, AND AFTER THE CIA

71. While "Cephalon had established a compliance program that meets the seven elements of effectiveness" set forth in OIG guidance prior to Cephalon's entry into the CIA, "[t]he CIA provided Cephalon with the opportunity to strengthen that program."[104] The requirements set forth in the CIA necessitated, among other changes, the introduction of the Standards of Global Business Practices (an international code of conduct),[105] re-branding the hotline and instituting a new phone number and email system for reporting any issues (including compliance-related issues),[106] reorganizing the Global Compliance Committee,[107] streamlining and updating numerous corporate and promotional policies, and hiring additional compliance professionals. Alongside these updates came additional

[104] Effectiveness of Cephalon's Global Compliance Program Board Update TEVA_MDL_A_04321682-87 (July 30, 2009).

[105] Standards of Global Business Practices ("Cephalon Code of Conduct"), TEVA_MDL_A_00552635-81 (2008).

[106] Reporting and Investigations of Misconduct (C-150), TEVA_MDL_A_00552585-88 (July 1, 2008).

[107] Charter of Cephalon's Global Compliance Committee, TEVA_MDL_A_00819644-45 (January 2009).

training, monitoring, and auditing programs as well as a continued commitment to the investigation and enforcement of circumstances constituting noncompliance.[108]

A. Restructuring of Corporate Compliance Framework

72. To ensure effective implementation of the CIA's requirements, Cephalon instituted an extensive framework to regulate all aspects of the company's business units and deter employees from violating relevant laws, regulations, procedures, and policies. Though it had already established a Chief Compliance Officer and Compliance Committee (meeting the OIG's Guidance's recommendation), Cephalon went further in late 2007 by creating a reconstituted Global Compliance Department ("Compliance"). This department was tasked with supporting the corporate compliance scheme, monitoring adherence to the CIA, and hiring four new compliance professionals.[109] In addition, Cephalon reorganized its Global Compliance Committee by adding new members that more broadly represent the company as a whole.[110] It also redesigned the PDRC in 2008, which was later renamed the PARC.[111]

73. In addition, in 2009, the Cephalon Activity Review and Evaluation ("CARE") committee was formed. This is a cross-functional team responsible for reviewing and evaluating initiatives, concepts, programs, and other activities involving healthcare professionals, to

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[108] Effectiveness of Cephalon's Global Compliance Program Board Update, TEVA_MDL_A_04321682-87 (July 30, 2009).

[109] 2008 Global Compliance Report, TEVA_MDL_A_00360420-52 (January 28, 2009); Effectiveness of Cephalon's Global Compliance Program Board Update, TEVA_MDL_A_04321682-87, at TEVA_MDL_A_04321683 (July 30, 2009).

[110] 2008 Global Compliance Report, TEVA_MDL_A_00360420-52 (January 28, 2009), at TEVA_MDL_A_00360421.

[111] Supra ¶ 36.

ensure these activities met the requirements set forth in the Company's U.S. Sales and Marketing Policy (GPO-100) and other relevant company policies and procedures.[112] Core functions represented include the marketing, compliance, medical, and legal departments. The CARE committee's Operations Procedure was set forth in Cephalon's GPO-114,[113] and then in Teva's U.S. Policy-115.[114] Most notably, the CARE committee focuses on reviewing activities such as: Speaker bureaus; Speaker training; Advisory boards; Consultant arrangements; Symposia; and Service arrangements with healthcare institutions or organizations.[115] Among other information, any application to CARE committee needs to (i) "describe the actual, bona fide and objective business need," and (ii) "[i]nclude the total compensation to be paid for the services and the factors influencing the determination of fair market value."[116]

B. Modification of Written Policies to Meet Additional CIA Requirements

74. Cephalon revised its pre-existing written policies and implemented several new policies and procedures in response to requirements set forth in the CIA. For instance, the 2009 "Speaker Bureau Management Procedure" reiterates that all speakers must go through a

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[112] Cephalon Activity Review & Evaluation (CARE) Process (GPO-114), TEVA_MDL_A_00552037-41 (Jan. 26, 2009).

[113] Id.

[114] *See* Centralized Activity Review and Evaluation (CARE) (US Policy-115), TEVA_MDL_A_00560852-1167, at TEVA_MDL_A_00560898 (July 1, 2012)

[115] Centralized Activity Review and Evaluation (CARE) (US Policy-115), TEVA_MDL_A_00560852-1167, at TEVA_MDL_A_00560898 (July 1, 2012).

[116] Cephalon Activity Review & Evaluation (CARE) Process (GPO-114), TEVA_MDL_A_00552037-41, at TEVA_MDL_A_00560899 (Jan. 26, 2009).

mandatory compliance training that specifically educated HCPs on the FDA promotion regulations.[117]

75. In 2012, after the acquisition of Cephalon by Teva USA, Teva USA implemented two policies related to educational grants, honoraria, and support. The "Independent Medical Education Grant Policy" emphasizes that it is impermissible for any Teva USA personnel or agent to control any aspect of an independent education activity and that grant support is independent of considerations of product promotion or sales.[118] The 2012 policy on "Payments to Healthcare Professionals Involved in Scientific and Medical-Related Activities" sets forth criteria for hiring an HCP based on medical expertise, not prescribing potential. These criteria are primarily focused on ensuring that the HCP is providing an actual, bona fide and objective business need.[119]

76. Cephalon's policy on the submission of medical requests also is supplemented by the pre-existing policy for Teva USA. The latter mandates that "[i]t is Teva's policy that sales representatives and other employees not solicit, either directly or indirectly, any questions from healthcare professionals ('HCPS') regarding off-label uses of Teva products. Sales representatives may not respond to any requests from HCPs for information about off-

[117] Speaker Bureau Management Procedure, TEVA_MDL_A_00953748-54 (Jan. 26, 2009).

[118] "Independent Medical Education Grants (US Policy-205)," in Centralized Activity Review and Evaluation (CARE) (US Policy-115), TEVA_MDL_A_00560852-1167, at TEVA_MDL_A_00560932 (July 1, 2012).

[119] Payments to Healthcare Professionals Involved in Scientific and Medical-Related Activities (US Policy 260), in Centralized Activity Review and Evaluation (CARE) (US Policy-115), TEVA_MDL_A_00560852-1167, at TEVA_MDL_A_00560943-44 (Sep. 17, 2012) ("Teva only seeks the services of adequately qualified HCPs for a sound business need or reason and always pays fair-market value for the services rendered. The same principles apply to our interactions with other organizations involved in scientific clinical or medical research sponsored or supported by Teva. ... The Healthcare Professional is: selected based on their qualification to render the services. [S]elected by Teva personnel qualified to assess the healthcare professional's expertise")

label uses of Company products, but must instead refer such inquiries to Teva U.S. Medical Information Department."[120]

77. Furthermore, Cephalon's pre-existing policy on reimbursement and prior authorization was further reaffirmed in the 2009 Cephalon "U.S. Sales and Marketing Policy" and in Teva USA's 2012 "Integrity Principle Policy." These policies further instruct that "it is never appropriate for a sales representative to suggest a code, diagnosis, or reimbursement strategy."[121]

C. Instituting Additional Training Programs

78. Cephalon developed a number of additional training programs after entering into the CIA in order to ensure employee adherence to new requirements and industry best practices.

79. In 2009, Cephalon instituted a new-hire training aiming to comply with the CIA as well as with the Anti-Kickback Law, the False Claims Act, FDA Promotional Regulations, PhRMA Code, and OIG Guidelines. Company representatives informed new employees that Cephalon's sales and marketing policy was governed by two guiding principles: (1) We don't buy business; and (2) Our promotional messages are always on-label, truthful and fair-balanced.[122]

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[120] Submission of Medical Requests (US Policy-215), TEVA_MDL_A_00553161-62 (July 1, 2012).

[121] US Sales and Marketing Policy, TEVA_MDL_A_00552730-65, at TEVA_MDL_A_00552762 (Jan. 2009); Teva Integrity Principle, TEVA_MDL_A_00553193-217 (2012).

[122] Compliance Overview Initial Training Class Presentation conducted by Karen Lowney, Senior Director, Global Compliance, TEVA_MDL_A_00801578-603, at TEVA_MDL_A_00801594 (Jan. 21, 2009).

80. In the following year, Cephalon added a new element to its new hire training regarding the company's philosophy on HCP targeting and call activity.[123] Cephalon made clear to new hires that the sales force was only to call on an HCP when it is "reasonable to believe that his or her practice includes patients that could be treated with a Cephalon product for an on-label indication, and, based on the nature of the HCP's practice, it is likely that he or she would treat the on-label condition."[124]

81. Lastly, in 2013, the company built in an assessment component of its new hire training that included modules on integrity principles, delivering promotional messages, interacting with HCPs, and ensuring scientific integrity, each of which required participants to score 80 percent or higher in order to receive credit.[125]

82. Cephalon's commitment to ensuring employee compliance extended beyond new hires. Updates to experienced employee training included the following new courses: a Standards Course, a Conflicts of Interest Course, a Promotional Practices Course, a DDMAC/FDA Regulations Course, Compliance Overview, and Home Study.[126] All U.S. employees took the "Standards Course" and a "Conflicts of Interest Course." As a supplement, the sales force took a "Promotional Practices" course, designed to provide employees with information about the regulatory environment, product promotion,

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[123] Compliance Overview Initial Training Class Presentation conducted by Karen Lowney, Senior Director, Global Compliance, TEVA_MDL_A_00381967-89, at TEVA_MDL_A_00381984 (Jan. 20, 2010).

[124] Compliance Overview Initial Training Class Presentation conducted by Karen Lowney, Senior Director, Global Compliance, TEVA_MDL_A_00381967-89, at TEVA_MDL_A_00381984 (Jan. 20, 2010). Emphasis in the original.

[125] Integrity In Focus: Products and Promotion, TEVA_MDL_A_00772936-149, at TEVA_MDL_A_00772949 (August 15, 2013).

[126] List of CIA-Required Trainings Attended by Company Employees as of 9/30/2009 – Reported to the OIG in CIA Annual Report Year 1, TEVA_MDL_A_00561764-2290, at TEVA_MDL_A_00561908 (2009).

interaction, hiring health care professionals, non-promotional interactions, and challenges. The lowest completion rate for a required training in any given year during the five-year reporting period under the CIA was 96 percent.[127]

83. Based on a review of training materials, one area of particular importance emphasized within both new hire and existing employee trainings was adhering to anti-kickback statues. For example, in a 2009 presentation, representatives were trained on the anti-kickback statute. The training included the basic elements of the anti-kickback statute, and provided additional information on the penalties associated with violations of the anti-kickback statute. The presentation also lists settlements within the pharmaceutical industry that involved pricing and kickback allegations in order to show the magnitude and severity of violations of the anti-kickback statute.[128] The presentation makes clear that Cephalon does not buy business, and provides additional information on the company's policies about payments to physicians.[129] These additional trainings and other compliance updates described above evidence that the CIA brought compliance to the forefront of nearly every function within the company.

[127] Within each CIA Annual Report Tab 5 provides a summary of the trainings provided pursuant to the CIA, as well as reports on completion percentages for employee training required by the CIA.

[128] InVentiv Health Care Compliance Training Interactions with Health Care Professionals, TEVA_MDL_A_11426483, pp. 39-44, (2009).

[129] InVentiv Health Care Compliance Training Interactions with Health Care Professionals, TEVA_MDL_A_11426483, pp. 8-9, (2009).

VI. OPINION #3: CEPHALON SUCCESSFULLY PASSED INDEPENDENT AUDITS REGARDING SALES AND MARKETING PRACTICES PURSUANT TO THE CIA.

84. Cephalon hired independent third parties to carry out audits of its relevant functions as mandated by the CIA and by the OIG Guidelines. The results from these audits and any follow-up action were reported in the annual OIG reports. The reports and Cephalon internal documents show that Cephalon satisfied all of the audit requirements imposed by the OIG. It is important to note that Cephalon had ceased promotion of Actiq well before the five-year CIA period, and has not promoted it since.

A. Independent Review Organization

85. Cephalon retained Ernst & Young LLP ("EY") to serve as the IRO from 2008 to 2014.[130] EY has a sterling reputation serving as the IRO for numerous CIAs. EY evaluated Cephalon's policies, procedures, and training, in addition to conducting analyses designed to identify potential off-label promotion and kickbacks. For each Reporting Period, EY presented its findings and recommendations to the OIG in the Annual IRO Report: Procedures, Findings and Recommendations. EY made three recommendations with respect to off-label information throughout the five years of auditing: (1) that "the Medical Sales Liaison Goals and Metrics document for each therapeutic area be updated to reflect the same emphasis the Medical Science Liaison Program policy reflects with respect to quality discussions as off-label, when necessary, and emphasizes the

[130] Report on Independent Review Organization's Engagement, TEVA_MDL_A_02939244-340, at TEVA_MDL_A_02939249 (September 30, 2009).

C. Field Force Monitoring Program

88. Cephalon compliance personnel conducted 30 full-day "ride-alongs" every year and reported observations to the OIG.[135] Incidence reports were compiled annually to properly record that potential issues were investigated appropriately. The 2009 "Global Compliance Incident Details Report" includes one reference to Fentora indicating that a "[Pain Care] sales representative called on a FENTORA [Do-Not-Call] HCP multiple times." This incident was noted during the monitoring activities and followed up by a written warning.[136]

89. The annual reports sent to the OIG show that any instance of potential promotional issues occurred in rare occasions. When Cephalon became aware of one of these occurrences, it took corrective action. For example, the first annual report documented two incidents of noncompliance for drugs other than Actiq or Fentora, and, in response, Cephalon took corrective action that included employment termination.[137] No instances of non-compliance related to Fentora were identified in the annual reports.

D. Message Recall Monitoring Program

90. Cephalon hired ZS Associates, a well-known analytic firm retained extensively by pharmaceutical companies, as an independent entity to analyze HCP recall of the marketing messages delivered by members of the sales force. During two one-week

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[135] Field Force Ride-Along Program (GC-220), TEVA_MDL_A_00552273-75 (Jan. 26, 2009).

[136] 2009 Global Compliance Incident Details Report, TEVA_MDL_A_00769186 (2009) (produced natively as an Excel spreadsheet – refer to last two tabs only).

[137] Summary of Field Force Monitoring Program," September 30, 2009, CIA Annual Report Year 1, TEVA_MDL_A_00561764-2290.

intervals each year, ZS interviewed approximately 300 detailed HCPs for message recall. If HCP participation rate was low, additional interview time occurred at a later period.[138]

91. The results of these message recall studies indicated that off-label conversations were a rare occurrence and, to the extent such conversations did occur, Cephalon took corrective measures. For example, the first CIA annual report documented ten instances of off-label discussions of Fentora. Cephalon undertook corrective action, including additional sales training. [139] By the fifth and final annual report, none of the Fentora sales calls were reported to contain any off-label discussions.[140]

[138] Teva Year 4 FENTORA Message Recall Surveys, TEVA_MDL_A_0561498-500.

[139] CIA Annual Report Year 1, TEVA_MDL_A_00561764-2290, at TEVA_MDL_A_00561774 (2009).

[140] CIA Annual Report Year 5, TEVA_MDL_A_00559116-998, at TEVA_MDL_A_00559732 (2013).